UNITED STATES DEPARTMENT OF COMMERCE
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FEB 27 1997

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 5,162,504 was filed on December 30, 1996 (certificate of mailing December 20, 1996), under 35 U.S.C. § 156. U.S. Patent No. 5,162,504 issued on November 10, 1992 from an application that was filed on June 3, 1988.

The assistance of your Office is requested in confirming that the product identified in the application, ProstaScint™, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. The application is considered to have been filed on December 20, 1996, the certificate of mailing date. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. However, it is noted that the description of the significant activities of the marketing applicant (Section numbered eleven in the application) does not appear to describe activities undertaken before the Food and Drug Administration by the marketing applicant in furtherance of the biologics license application. On February 26, 1997, in response to a telephone call from the undersigned, Mr. W. Scott McNees of Cytogen Corporation indicated that he will be filing a supplement to the application which further describes the relevant activities of the marketing applicant. A copy will be forwarded to your Office with any request for determination of the regulatory review period.

Telephone inquiries regarding this communication should be directed to the undersigned at (703) 306-3159.

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: W. Scott McNees
Cytogen Corporation
600 College Road East
Princeton, NJ 08540